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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/853,427 | 05/10/2001 | James Mullin | MUL01-NP001 | 6770 |

24358 7590 01/21/2003

THOMAS JEFFERSON UNIVERSITY
INTELLECTUAL PROPERTY DIVISION
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SUITE 620
PHILADELPHIA, PA 19107

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| EXAMINER |
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UNGAR, SUSAN NMN

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| ART UNIT | PAPER NUMBER |
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1642

DATE MAILED: 01/21/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/853,427

Applicant(s)
Mullin et al

Examiner
Ungar

Art Unit
1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Nov 29, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-12 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 3-12 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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1. The Election filed November 29, 2002 (Paper No. 7) in response to the Office Action of July 24, 1996 is acknowledged and has been entered. Claims 11 and 2 have been canceled, claim 3 has been amended and claims 5-12 have been added. Claims 3-12 are currently under prosecution.

2. Applicant's election with traverse of Group III, claims 3-4 and the species of sucrose and enzymatic assay in Paper No 7 is acknowledged. The traversal of the species election requirement of sucrose is on the grounds that the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden. The argument has been considered but has not been found persuasive because, regardless of similarity of structure and property as described by Applicant, the species are not obvious one over the other and the literature search, particularly relevant in this art, is not coextensive and is much more important in evaluating the burden of search . Different searches and issues are involved in the examination of each species and given the complexity of the claimed invention, search of all species would be an undue burden. Further the traversal of the species requirement of enzymatic assay is on the grounds that the use of the assay method does not affect the novelty or patentability of the claimed invention and does not make the species patentably distinct. The argument has been considered but has not been found persuasive because although the assay method does not affect the novelty or patentability of the claimed invention, the assay methods are indeed distinct and the literature search, particularly relevant in this art, is not coextensive and is much more important in evaluating the burden of search . Different searches and issues are involved in the

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examination of each species and given the complexity of the claimed invention, search of all species would be an undue burden. For these reasons the restriction requirement is deemed to be proper and is therefore made FINAL.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, drawn to the restriction between Groups III and IV, the election of Group III has been treated as an election without traverse (MPEP 818.03(a)).

3. Upon review and reconsideration and in view of the newly added claims, Restriction to one of the following inventions is required under 35 U.S.C. § 121 because this application contains claims directed to the following patentably distinct species of the claimed invention:

Claims 3 and 10 are generic to a plurality of disclosed patentably distinct species comprising methods wherein TJ leakiness is correlated with different cellular phenomena with different structures, functions wherein the phenomena are (a) altered expression of alpha PKC (claims 8 and 11), (b) altered expression of ZO-1 (claims 8 and 11), reduced phosphorylation state of occludin (claims 9 and 12).

4. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

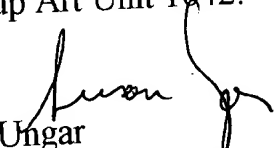
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.


Susan Ungar
Primary Patent Examiner
January 14, 2003